Medical Information Request: JELMYTO® (mitomycin) for pyelocalyceal solution.
Thank you for your question regarding the Uroject12 Syringe Lever (includes versions with plastic [polyamide] knob and metal [aluminum] knob) used with the instillation of JELMYTO.

Please refer to the Instructions for Use (IFU) which applies to the Uroject12 Syringe Lever (includes versions with **either plastic or metal** knob for detailed information on the cleaning, disinfection, and sterilization procedures available on: https://www.urogen.com/download/pdf/uroject12-syringe-lever-instructions.pdf)

Procedures described in the IFU were qualified and reviewed by the FDA. Alternate procedures for cleaning, disinfection, and sterilization may be utilized if they are equivalent to the recommendations in the IFU; however, only the procedures included in the IFU were qualified and reviewed by the FDA.

As part of the Uroject12 Syringe Lever (USL) life cycle management, a design review was performed, and it was decided to modify the Syringe Lever knob material from polyamide to aluminum to be similar to the other material parts of the USL device.

The revised Knob is made of aluminum alloy 6082 and is manufactured by the same manufacturer. This material is from the aluminum family and has similar resistance to corrosion as the 6061 alloy which is already used extensively in the current device design.

UroGen completed a comprehensive risk assessment process, following FDA Guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device" comparing various aspects of functionality between the USL with polyamide (plastic) knob and aluminum (metal) knob.

The aluminum knob is stronger than the current polyamide knob and has very similar geometry. Therefore, the performance of the device after repeated operation will not be affected by the change in material. In addition, the knob will be anodized to ensure keeping similar surface properties on all aluminum parts of the USL device. Therefore, the new material will not be affected by any labeled cleaning, disinfection, and/or sterilization process of the device. No additional verification/validation activities are required.

Please refer to the attachments below for detailed information on the preparation and administration of JELMYTO:

- INSTRUCTIONS FOR PHARMACY (IFP)
- INSTRUCTIONS FOR ADMINISTRATION (IFA)

Please refer to the package insert and www.jelmyto.com for the full Prescribing Information.

As described in the JELMYTO® (mitomycin) for pyelocalyceal solution Prescribing Information:

• INDICATIONS AND USAGE: JELMYTO is an alkylating drug indicated for the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUC).

• ADVERSE REACTIONS: The most common adverse reactions (≥ 20%) are ureteric obstruction, flank pain, urinary tract infection, hematuria, renal dysfunction, nausea, abdominal pain, fatigue, dysuria, and vomiting.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit http://www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to UroGen Pharma at 1-855-987-6436.

References:

400 Alexander Park Drive, 4th Floor, Princeton, NJ 08540 | 646-768-9780

1. JELMYTO® (mitomycin) for pyelocalyceal solution. Prescribing Information 2024. UroGen Pharma, Princeton, New Jersey.
2. Data on file. UroGen Pharma.
3. JELMYTO® and UroGen® are trademarks of UroGen Pharma, Ltd. All other trademarks are the property of their respective owners.

Attachments:

- JELMYTO® (mitomycin) for pyelocalyceal solution. Prescribing Information 2024
- JELMYTO® (mitomycin) for pyelocalyceal solution. Instructions for Pharmacy (IFP)
- JELMYTO® (mitomycin) for pyelocalyceal solution. Instructions for Administration (IFA)
- Uroject12 Syringe Lever. Instruction for Use (IFU)

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